

The management system of

# DENTSPLY Implants NV

Research Campus 10  
3500 Hasselt, Belgium

has been assessed and certified as meeting the requirements of

## ISO 13485:2003 EN ISO 13485:2012



For the following activities

**Design, development, manufacture and distribution of  
non-sterile surgical guides,  
medical image processing, simulation and design software  
medical models  
for the area of dentistry.  
Customer servicing and training to customers.**

This certificate is valid from 17 October 2014 until 24 February 2017 and  
remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 24 January 2017.  
Issue 5. Certified since 25 April 2012.

This is a multi-site certification.  
Additional site details are listed on the subsequent page.

Authorised by

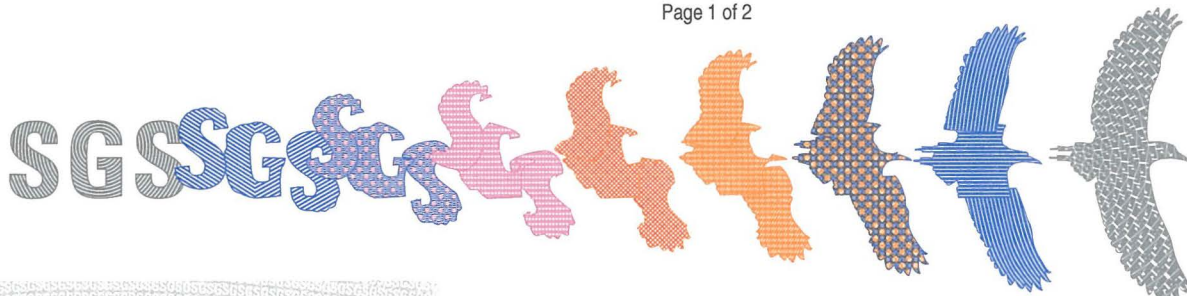
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# DENTSPLY Implants NV

## ISO 13485:2003 EN ISO 13485:2012

Issue 5

Detailed scope

**Dentsply Implants N.V. (site Hasselt):**  
Design, development, manufacture and distribution of  
non-sterile surgical guides,  
medical models  
for the area of dentistry.

**Dentsply Implants N.V. (site Leuven):**  
Design, development, manufacture and distribution of  
medical image processing, simulation and design software  
for the area of dentistry.

Design, development of  
non-sterile surgical guides,  
medical models  
for the area of dentistry.

Customer servicing and training to customers.

**Materialise Dental Ukraine LLC:**  
Design, development and manufacture of  
medical image processing, simulation and design software  
medical models  
for the area of dentistry.

Additional facilities

**Dentsply Implants N.V. (site Hasselt)**  
Research Campus 10  
3500 Hasselt, Belgium

**Dentsply Implants N.V. (site Leuven)**  
Grensstraat 1B  
3010 Kessel-Lo, Belgium

**Materialise Dental Ukraine LLC**  
Raisy Okypnoi 8A  
02002 Kyiv, Ukraine



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